K 122251

JAN 2 4 2013

510(k) Summary for the
Quantel Medical VITRA MULTISPOT

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: Quantel Medical
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Summary Preparation Date: January 23, 2013

2. Names

Device Name: VITRA MULTISPOT

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Device

- Quantel Medical SUPRA SCAN™ Delivery System coupled to a SUPRA 532 (K100678)
- Quantel Medical VITRA (K043236)
- OPTIMEDICA CORPORATION PASCAL Photocoagulator (K043486)
- OPTIMEDICA CORPORATION PASCAL Synthesis Delivery System (K081744)

4. Device Description

VITRA MULTISPOT is a laser photocoagulator emitting a treatment beam of green (532nm) laser radiation. The treatment beam is delivered through a delivery system and is aimed using a Red Laser diode (635-650nm).

The Quantel Medical VITRA MULTISPOT Laser can be connected with the following delivery systems:

1) Scanning Laser Delivery System adaptor
2) Slit Lamp adaptor
3) Indirect ophthalmoscope adaptor

Output power from all these delivery systems are calibrated to deliver a maximum of 1.5 watts. The control box is a tactile LCD screen which is part of the main housing.

5. Indications for Use

The VITRA MULTISPOT Laser is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation and pan retinal photocoagulation for vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy;
- Choroidal neovascularization;
- Branch retinal vein occlusion;
- Treatment of choroidal neovascularization associated with wet Age-related macular degeneration;
- Retinal tears and detachments
- Macular edema
- Retinopathy of prematurity
- Iridotomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

6. Substantial Equivalence

The VITRA MULTISPOT Laser shares the same intended use and safety compliance, similar design features, functional features, and therefore is substantially equivalent to the predicate devices, the PASCAL Photocoagulator (K043486) and Synthesis Delivery System (K081744), VITRA (K043236) and the Quantel Medical SUPRA SCAN™ Delivery System coupled to the SUPRA 532 (K100678). In addition, a review of the predicate devices demonstrates that the VITRA MULTISPOT Laser is substantially equivalent to the predicate

devices as they share equivalent specifications / characteristics and are used to perform the same indicated surgical procedures.

7. Performance Data

Laboratory testing was conducted to validate and verify that the VITRA MULTISPOT Laser met all design specifications and was substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quantel Medical
% O'Connell Regulatory Consultants, Incorporated
Ms. Maureen O'Connell
Regulatory Counsultant
5 Timber Lane
North Reading, Massachusetts 01864

January 24. 2013

Re: K122251
Trade/Device Name: VITRA MULTISPOT
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 12, 2012
Received: December 13, 2012

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122251

Device Name: VITRA MULTISPOT

Indications for Use:

The VITRA MULTISPOT Laser photocoagulator is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy;
- Choroidal neovascularization;
- Branch retinal vein occlusion;
- Treatment of choroidal neovascularization associated with wet Age-related macular degeneration;
- Retinal tears and detachments
- Macular edema
- Retinopathy of Prematurity
- Iridotomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for mkm
Division of Surgical Devices
510(k) Number K122251